

JS 44 (Rev 02/19)

CIVIL COVER SHEET

The JS 44 civil cover sheet and the information contained herein neither replace nor supplement the filing and service of pleadings or other papers as required by law, except as provided by local rules of court. This form, approved by the Judicial Conference of the United States in September 1974, is required for the use of the Clerk of Court for the purpose of initiating the civil docket sheet. (SEE INSTRUCTIONS ON NEXT PAGE OF THIS FORM.)

I. (a) PLAINTIFFS

Paul Molloy and Jacqueline Molloy, h/w on behalf of themselves and all others similarly situated

(b) County of Residence of First Listed Plaintiff **Delaware County**
(EXCEPT IN U.S. PLAINTIFF CASES)

(c) Attorneys (Firm Name, Address, and Telephone Number)

David S. Senoff, Esquire & Hillary B. Weinstein, Esquire - First Law Strategy Group, I.L.C., 121 S. Broad St., Ste 300, Phila., PA 19107
Richard Ochroch, Esquire & Brett Benton, Esquire - Richard M. Ochroch & Assoc., 318 S. 16th St., Philadelphia, PA 190102

DEFENDANTS

Aetna Life Insurance Company and Aetna, Inc.

County of Residence of First Listed Defendant **Hartford County**
(IN U.S. PLAINTIFF CASES ONLY)

NOTE: IN LAND CONDEMNATION CASES, USE THE LOCATION OF THE TRACT OF LAND INVOLVED

Attorneys (If Known)

II. BASIS OF JURISDICTION (Place an "X" in One Box Only)

- ☐ 1 U.S. Government Plaintiff
- ☒ 3 Federal Question (U.S. Government Not a Party)
- ☐ 2 U.S. Government Defendant
- ☐ 4 Diversity (Indicate Citizenship of Parties in Item III)

III. CITIZENSHIP OF PRINCIPAL PARTIES (Place an "X" in One Box for Plaintiff and One Box for Defendant)

- | | PTF | DEF | | PTF | DEF |
|---|----------------------------|----------------------------|---|----------------------------|----------------------------|
| Citizen of This State | <input type="checkbox"/> 1 | <input type="checkbox"/> 1 | Incorporated or Principal Place of Business In This State | <input type="checkbox"/> 4 | <input type="checkbox"/> 4 |
| Citizen of Another State | <input type="checkbox"/> 2 | <input type="checkbox"/> 2 | Incorporated and Principal Place of Business In Another State | <input type="checkbox"/> 5 | <input type="checkbox"/> 5 |
| Citizen or Subject of a Foreign Country | <input type="checkbox"/> 3 | <input type="checkbox"/> 3 | Foreign Nation | <input type="checkbox"/> 6 | <input type="checkbox"/> 6 |

IV. NATURE OF SUIT (Place an "X" in One Box Only)

Click here for: Nature of Suit Code Descriptions.

CONTRACT	TORTS	FORFEITURE/PENALTY	BANKRUPTCY	OTHER STATUTES
<input type="checkbox"/> 110 Insurance <input type="checkbox"/> 120 Marine <input type="checkbox"/> 130 Miller Act <input type="checkbox"/> 140 Negotiable Instrument <input type="checkbox"/> 150 Recovery of Overpayment & Enforcement of Judgment <input type="checkbox"/> 151 Medicare Act <input type="checkbox"/> 152 Recovery of Defaulted Student Loans (Excludes Veterans) <input type="checkbox"/> 153 Recovery of Overpayment of Veteran's Benefits <input type="checkbox"/> 160 Stockholders' Suits <input type="checkbox"/> 190 Other Contract <input type="checkbox"/> 195 Contract Product Liability <input type="checkbox"/> 196 Franchise	PERSONAL INJURY <input type="checkbox"/> 310 Airplane <input type="checkbox"/> 315 Airplane Product Liability <input type="checkbox"/> 320 Assault, Libel & Slander <input type="checkbox"/> 330 Federal Employers' Liability <input type="checkbox"/> 340 Marine <input type="checkbox"/> 345 Marine Product Liability <input type="checkbox"/> 350 Motor Vehicle <input type="checkbox"/> 355 Motor Vehicle Product Liability <input type="checkbox"/> 360 Other Personal Injury <input type="checkbox"/> 362 Personal Injury - Medical Malpractice	PERSONAL INJURY <input type="checkbox"/> 365 Personal Injury - Product Liability <input type="checkbox"/> 367 Health Care/Pharmaceutical Personal Injury Product Liability <input type="checkbox"/> 368 Asbestos Personal Injury Product Liability PERSONAL PROPERTY <input type="checkbox"/> 370 Other Fraud <input type="checkbox"/> 371 Truth in Lending <input type="checkbox"/> 380 Other Personal Property Damage <input type="checkbox"/> 385 Property Damage Product Liability	<input type="checkbox"/> 625 Drug Related Seizure of Property 21 USC 881 <input type="checkbox"/> 690 Other	<input type="checkbox"/> 422 Appeal 28 USC 158 <input type="checkbox"/> 423 Withdrawal 28 USC 157 PROPERTY RIGHTS <input type="checkbox"/> 820 Copyrights <input type="checkbox"/> 830 Patent <input type="checkbox"/> 835 Patent - Abbreviated New Drug Application <input type="checkbox"/> 840 Trademark SOCIAL SECURITY <input type="checkbox"/> 861 HIA (1395ff) <input type="checkbox"/> 862 Black Lung (923) <input type="checkbox"/> 863 DIWC/DIWW (405(g)) <input type="checkbox"/> 864 SSID Title XVI <input type="checkbox"/> 865 RSI (405(g))
REAL PROPERTY <input type="checkbox"/> 210 Land Condemnation <input type="checkbox"/> 220 Foreclosure <input type="checkbox"/> 230 Rent Lease & Ejectment <input type="checkbox"/> 240 Torts to Land <input type="checkbox"/> 245 Tort Product Liability <input type="checkbox"/> 290 All Other Real Property	CIVIL RIGHTS <input type="checkbox"/> 440 Other Civil Rights <input type="checkbox"/> 441 Voting <input type="checkbox"/> 442 Employment <input type="checkbox"/> 443 Housing/Accommodations <input type="checkbox"/> 445 Amer w/Disabilities - Employment <input type="checkbox"/> 446 Amer w/Disabilities - Other <input type="checkbox"/> 448 Education	PRISONER PETITIONS Habeas Corpus: <input type="checkbox"/> 463 Alien Detainee <input type="checkbox"/> 510 Motions to Vacate Sentence <input type="checkbox"/> 530 General <input type="checkbox"/> 535 Death Penalty Other: <input type="checkbox"/> 540 Mandamus & Other <input type="checkbox"/> 550 Civil Rights <input type="checkbox"/> 555 Prison Condition <input type="checkbox"/> 560 Civil Detainee - Conditions of Confinement	<input type="checkbox"/> 710 Fair Labor Standards Act <input type="checkbox"/> 720 Labor/Management Relations <input type="checkbox"/> 740 Railway Labor Act <input type="checkbox"/> 751 Family and Medical Leave Act <input type="checkbox"/> 790 Other Labor Litigation <input checked="" type="checkbox"/> 791 Employee Retirement Income Security Act	<input type="checkbox"/> 375 False Claims Act <input type="checkbox"/> 376 Qui Tam (31 USC 3729(a)) <input type="checkbox"/> 400 State Reapportionment <input type="checkbox"/> 410 Antitrust <input type="checkbox"/> 430 Banks and Banking <input type="checkbox"/> 450 Commerce <input type="checkbox"/> 460 Deportation <input type="checkbox"/> 470 Racketeer Influenced and Corrupt Organizations <input type="checkbox"/> 480 Consumer Credit <input type="checkbox"/> 485 Telephone Consumer Protection Act <input type="checkbox"/> 490 Cable/Sat TV <input type="checkbox"/> 490 Securities/Commodities/Exchange <input type="checkbox"/> 890 Other Statutory Actions <input type="checkbox"/> 891 Agricultural Acts <input type="checkbox"/> 893 Environmental Matters <input type="checkbox"/> 895 Freedom of Information Act <input type="checkbox"/> 896 Arbitration <input type="checkbox"/> 899 Administrative Procedure Act/Review or Appeal of Agency Decision <input type="checkbox"/> 950 Constitutionality of State Statutes
			IMMIGRATION <input type="checkbox"/> 462 Naturalization Application <input type="checkbox"/> 465 Other Immigration Actions	FEDERAL TAX SUITS <input type="checkbox"/> 870 Taxes (U.S. Plaintiff or Defendant) <input type="checkbox"/> 871 IRS—Third Party 26 USC 7609

V. ORIGIN (Place an "X" in One Box Only)

- ☒ 1 Original Proceeding
- ☐ 2 Removed from State Court
- ☐ 3 Remanded from Appellate Court
- ☐ 4 Reinstated or Reopened
- ☐ 5 Transferred from Another District (specify)
- ☐ 6 Multidistrict Litigation - Transfer
- ☐ 8 Multidistrict Litigation - Direct File

VI. CAUSE OF ACTION

Cite the U.S. Civil Statute under which you are filing (Do not cite jurisdictional statutes unless diversity):
29 U.S.C. §1001, et seq.

Brief description of cause:
Class Action Complaint challenging Defendants' improper denial of medically necessary cancer treatment under ERISA.

VII. REQUESTED IN COMPLAINT:

☒ CHECK IF THIS IS A CLASS ACTION UNDER RULE 23, F.R.Cv.P.

DEMAND \$

CHECK YES only if demanded in complaint:

JURY DEMAND: ☒ Yes ☐ No

VIII. RELATED CASE(S) IF ANY

(See Instructions):

JUDGE

DOCKET NUMBER

DATE

August 28, 2019

SIGNATURE OF ATTORNEY OF RECORD

Paul Molloy

FOR OFFICE USE ONLY

RECEIPT #

AMOUNT

APPLYING IFP

JUDGE

MAG JUDGE

UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

DESIGNATION FORM

(to be used by counsel or pro se plaintiff to indicate the category of the case for the purpose of assignment to the appropriate calendar)

Address of Plaintiff: 8 Surrey Drive, Newtown Square, PA 19073

Address of Defendant: 151 Farmington Avenue, Hartford, CT 06156

Place of Accident, Incident or Transaction: Pennsylvania

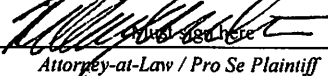
RELATED CASE, IF ANY:

Case Number: _____ Judge: _____ Date Terminated: _____

Civil cases are deemed related when *Yes* is answered to any of the following questions:

- | | | |
|--|------------------------------|--|
| 1. Is this case related to property included in an earlier numbered suit pending or within one year previously terminated action in this court? | Yes <input type="checkbox"/> | No <input checked="" type="checkbox"/> |
| 2. Does this case involve the same issue of fact or grow out of the same transaction as a prior suit pending or within one year previously terminated action in this court? | Yes <input type="checkbox"/> | No <input checked="" type="checkbox"/> |
| 3. Does this case involve the validity or infringement of a patent already in suit or any earlier numbered case pending or within one year previously terminated action of this court? | Yes <input type="checkbox"/> | No <input checked="" type="checkbox"/> |
| 4. Is this case a second or successive habeas corpus, social security appeal, or pro se civil rights case filed by the same individual? | Yes <input type="checkbox"/> | No <input checked="" type="checkbox"/> |

I certify that, to my knowledge, the within case ☐ is / ☒ is not related to any case now pending or within one year previously terminated action in this court except as noted above.

DATE: 08/28/2019  209533
Attorney-at-Law / Pro Se Plaintiff Attorney I.D. # (if applicable)

CIVIL: (Place a ☒ in one category only)

A. Federal Question Cases:

- ☐ 1. Indemnity Contract, Marine Contract, and All Other Contracts
- ☐ 2. FELA
- ☐ 3. Jones Act-Personal Injury
- ☐ 4. Antitrust
- ☐ 5. Patent
- ☐ 6. Labor-Management Relations
- ☐ 7. Civil Rights
- ☐ 8. Habeas Corpus
- ☐ 9. Securities Act(s) Cases
- ☐ 10. Social Security Review Cases
- ☒ 11. All other Federal Question Cases
(Please specify): ERISA, 29 U.S.C. § 1001, et seq.

B. Diversity Jurisdiction Cases:

- ☐ 1. Insurance Contract and Other Contracts
- ☐ 2. Airplane Personal Injury
- ☐ 3. Assault, Defamation
- ☐ 4. Marine Personal Injury
- ☐ 5. Motor Vehicle Personal Injury
- ☐ 6. Other Personal Injury (Please specify): _____
- ☐ 7. Products Liability
- ☐ 8. Products Liability – Asbestos
- ☐ 9. All other Diversity Cases
(Please specify): _____

ARBITRATION CERTIFICATION

(The effect of this certification is to remove the case from eligibility for arbitration.)

I, Hillary B. Weinstein, counsel of record or pro se plaintiff, do hereby certify:

☒ Pursuant to Local Civil Rule 53.2, § 3(c) (2), that to the best of my knowledge and belief, the damages recoverable in this civil action case exceed the sum of \$150,000.00 exclusive of interest and costs:

☒ Relief other than monetary damages is sought.

DATE: 08/28/2019  209533
Attorney-at-Law / Pro Se Plaintiff Attorney I.D. # (if applicable)

NOTE: A trial de novo will be a trial by jury only if there has been compliance with F.R.C.P. 38.

**UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA**

DESIGNATION FORM

(to be used by counsel or pro se plaintiff to indicate the category of the case for the purpose of assignment to the appropriate calendar)

Address of Plaintiff: 8 Surrey Drive, Newtown Square, PA 19073
 Address of Defendant: 151 Farmington Avenue, Hartford, CT 06156
 Place of Accident, Incident or Transaction: Pennsylvania

RELATED CASE, IF ANY:

Case Number: _____ Judge: _____ Date Terminated: _____

Civil cases are deemed related when *Yes* is answered to any of the following questions:

- | | | |
|--|------------------------------|--|
| 1. Is this case related to property included in an earlier numbered suit pending or within one year previously terminated action in this court? | Yes <input type="checkbox"/> | No <input checked="" type="checkbox"/> |
| 2. Does this case involve the same issue of fact or grow out of the same transaction as a prior suit pending or within one year previously terminated action in this court? | Yes <input type="checkbox"/> | No <input checked="" type="checkbox"/> |
| 3. Does this case involve the validity or infringement of a patent already in suit or any earlier numbered case pending or within one year previously terminated action of this court? | Yes <input type="checkbox"/> | No <input checked="" type="checkbox"/> |
| 4. Is this case a second or successive habeas corpus, social security appeal, or pro se civil rights case filed by the same individual? | Yes <input type="checkbox"/> | No <input checked="" type="checkbox"/> |

I certify that, to my knowledge, the within case ☐ is / ☒ is not related to any case now pending or within one year previously terminated action in this court except as noted above.

DATE: 08/28/2019 _____ Must sign here _____ 209533
Attorney-at-Law / Pro Se Plaintiff *Attorney I.D. # (if applicable)*

CIVIL: (Place a ✓ in one category only)

A. Federal Question Cases:

- ☐ 1. Indemnity Contract, Marine Contract, and All Other Contracts
☐ 2. FELA
☐ 3. Jones Act-Personal Injury
☐ 4. Antitrust
☐ 5. Patent
☐ 6. Labor-Management Relations
☐ 7. Civil Rights
☐ 8. Habeas Corpus
☐ 9. Securities Act(s) Cases
☐ 10. Social Security Review Cases
☒ 11. All other Federal Question Cases
 (Please specify): ERISA, 29 U.S.C. § 1001, et seq.

B. Diversity Jurisdiction Cases:

- ☐ 1. Insurance Contract and Other Contracts
☐ 2. Airplane Personal Injury
☐ 3. Assault, Defamation
☐ 4. Marine Personal Injury
☐ 5. Motor Vehicle Personal Injury
☐ 6. Other Personal Injury (Please specify): _____
☐ 7. Products Liability
☐ 8. Products Liability – Asbestos
☐ 9. All other Diversity Cases
 (Please specify): _____

ARBITRATION CERTIFICATION

(The effect of this certification is to remove the case from eligibility for arbitration.)

I, Hillary B. Weinstein, counsel of record or pro se plaintiff, do hereby certify:

- ☒ Pursuant to Local Civil Rule 53.2, § 3(c) (2), that to the best of my knowledge and belief, the damages recoverable in this civil action case exceed the sum of \$150,000.00 exclusive of interest and costs:
☒ Relief other than monetary damages is sought.

DATE: 08/28/2019 _____ 209533
Attorney-at-Law / Pro Se Plaintiff *Attorney I.D. # (if applicable)*

NOTE: A trial de novo will be a trial by jury only if there has been compliance with F.R.C.P. 38.

**IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA**

CASE MANAGEMENT TRACK DESIGNATION FORM

Paul Molloy and Jacqueline Molloy, h/w, on	:	
behalf of themselves and all others similarly situated	:	CIVIL ACTION
v.	:	
	:	
Aetna Life Insurance Company and Aetna, Inc.	:	NO.


In accordance with the Civil Justice Expense and Delay Reduction Plan of this court, counsel for plaintiff shall complete a Case Management Track Designation Form in all civil cases at the time of filing the complaint and serve a copy on all defendants. (See § 1:03 of the plan set forth on the reverse side of this form.) In the event that a defendant does not agree with the plaintiff regarding said designation, that defendant shall, with its first appearance, submit to the clerk of court and serve on the plaintiff and all other parties, a Case Management Track Designation Form specifying the track to which that defendant believes the case should be assigned.

SELECT ONE OF THE FOLLOWING CASE MANAGEMENT TRACKS:

- (a) Habeas Corpus – Cases brought under 28 U.S.C. § 2241 through § 2255. ()
- (b) Social Security – Cases requesting review of a decision of the Secretary of Health and Human Services denying plaintiff Social Security Benefits. ()
- (c) Arbitration – Cases required to be designated for arbitration under Local Civil Rule 53.2. ()
- (d) Asbestos – Cases involving claims for personal injury or property damage from exposure to asbestos. ()
- (e) Special Management – Cases that do not fall into tracks (a) through (d) that are commonly referred to as complex and that need special or intense management by the court. (See reverse side of this form for a detailed explanation of special management cases.) ()
- (f) Standard Management – Cases that do not fall into any one of the other tracks. (x)

August 28, 2019

Date


Attorney-at-law

Plaintiffs

Attorney for

(215) 258-4700

(215) 258-4777

hweinstein@firstlawstrategy.com

Telephone

FAX Number

E-Mail Address

**IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA**

Paul Molloy and Jacqueline Molloy, h/w	:	CIVIL ACTION
on behalf of themselves and all others	:	CLASS ACTION
similarly situated,	:	
	:	COMPLAINT
	:	JURY TRIAL DEMANDED
Plaintiffs,	:	
	:	No.
v.	:	
	:	
Aetna Life Insurance Company and	:	
Aetna Inc.	:	
	:	
Defendants.	:	
	:	

PLAINTIFF’S CLASS ACTION COMPLAINT

Plaintiffs, Paul Molloy and Jacqueline Molloy, husband and wife, (“Plaintiffs”), and adult citizens of the Commonwealth of Pennsylvania, individually and upon behalf of all others similarly situated, by and through their attorneys First Law Strategy Group, LLC; and Richard M. Ochroch & Associates, P.C., hereby bring this action seeking relief from Aetna Life Insurance Company and Aetna Inc. (collectively, “Aetna” or “Defendants”) which have their principal place of business located at the addresses identified above, and alleges as follows based upon personal knowledge, and together with their own acts and experiences, and as to all other matters, based upon information and belief, including investigation conducted by Plaintiffs’ attorneys, the undersigned.

I. INTRODUCTION

1. This is a class action brought pursuant to the Employee Retirement Income Security Act of 1974, 29 U.S.C. §1001, *et seq.*, on behalf of members, participants, and beneficiaries of an employee welfare benefit plan (“Plan”) administered by Aetna Life Insurance Company (through

its parent company Aetna Inc.) who were denied proton beam therapy (“Proton Beam Therapy” or “PBT”) due to Aetna’s uniform application of an arbitrary medical policy, despite Aetna’s statutorily mandated requirement to act as fiduciaries with respect to the Plan solely in the interest of the participants and beneficiaries and for the exclusive purpose of: (1) providing benefits to participants and their beneficiaries; and (2) defraying reasonable expenses of administering the plan. Due to this breach of fiduciary duty, Aetna violated its own statements to plan participants and beneficiaries to the contrary when it stated that it would, in fact, deliver access to medically necessary healthcare for the treatment of cancer.

2. At the crux of this case is what happens when a duly-licensed physician prescribes appropriate treatment, like Proton Beam Therapy, which has been recognized for decades by the medical community and the FDA as an established, medically appropriate treatment for cancer, and thereafter the fiduciary-insurer of an ERISA-regulated employee welfare benefit plan substitutes its judgment for that of the treating physician and denies the treatment as not “medically necessary” and as “experimental or investigational.”

3. Plaintiff, Paul Molloy (“Paul”), is currently a young, healthy, 36-year old man who underwent brain surgery for a tumor located in his right temporal lobe. Following successful surgery and removal of approximately 80% of his tumor, his doctors recommended post-operative radiation, specifically with Proton Beam Therapy, at the Penn Medicine Roberts Proton Therapy Center, which is part of the Hospital of the University of Pennsylvania (“HUP”). HUP is a world class medical, research and teaching facility located in Philadelphia, Pennsylvania.

4. Plaintiff’s own medical team concluded that Proton Beam Therapy is considered more accurate than other available radiation treatments such as traditional photon, *i.e.*, x-ray, radiation as it allows the physician to deliver full or higher doses of radiation while sparing

surrounding healthy tissues and organs. Proton Beam Therapy can also reduce the risk of a second malignancy by reducing the volume of radiated normal tissue.

5. Accordingly, for patients like Paul, Proton Beam Therapy is a more effective treatment than other radiotherapies given, in that it not only destroys the tumor, but also reduces the risk of recurrence. And, importantly for Paul, Proton Beam Therapy reduces the risk of long-term (even permanent) neurocognitive side effects associated with irradiating parts of the brain that surround the tumor which do not themselves require radiation but are irradiated nonetheless, due to their proximity to the tumor.

6. Indeed, for those in Paul's position who have been prescribed Proton Beam Therapy, this type of radiation is the only kind that could not only help cure their cancer, but also significantly limit radiation exposure and resulting damage to surrounding healthy cells, tissues, or organs.

7. In fact, Proton Beam Therapy is approved for use by other private (commercial) and government sponsored health insurance companies.

8. Proton Beam Therapy has also been approved by the FDA for treatment of cancer since 1988.

9. The currently available data reveals that there are 27 operational proton therapy centers in the United States, the majority of them having been constructed since 2010. Indeed, the Roberts Proton Therapy Center at the Penn Abramson Cancer Center was built in 2010 for just this purpose. It is the largest facility in the world for the use of this therapy and is the only proton therapy center that is fully integrated with a National Cancer Institute (NCI) designated comprehensive cancer center.

10. Despite the benefits of Proton Beam Therapy, the proliferation of proton therapy centers, and the payment for Proton Beam Therapy by other private insurers and government-sponsored insurance plans, Aetna denied Paul's pre- and post-operative requests for approval of his Proton Beam Therapy, ignoring Paul's own physician's advice¹, and instead of acting in Paul's interests and the interests of all Aetna members, participants and beneficiaries of its health insurance plans.

11. Aetna's multiple denials of Paul's requests for Proton Beam Therapy were for specious reasons, claiming that the procedure is "experimental and investigational." Notwithstanding Aetna's labeling Proton Beam Therapy as "experimental and investigational,"² Proton Beam Therapy has been in existence, and producing successful outcomes, for decades.

12. In truth, Proton Beam Therapy costs more than traditional radiation (*i.e.*, photon therapy); and this is the actual (yet unstated) reason for Aetna's denial.

13. Undeterred by Aetna's denials and claims that Proton Beam Therapy was "experimental and investigational," Paul trusted Dr. Lustig and paid for the Proton Beam Therapy treatment from his own funds. As a result of the Proton Beam Therapy, Paul has thankfully had positive results and has had no evidence of recurrence of the cancer a year-and-a-half after treatment, with no discernible side effects from radiation.

14. Plaintiffs have therefore brought this class action on behalf of themselves and all others similarly situated so that this Court can determine whether Aetna's "one-size fits all"

¹Paul's main physician is Dr. Robert Lustig, Chief of Clinical Operations in Radiation Oncology at Penn Medicine, a Professor of Clinical Radiation Oncology at the University of Pennsylvania School of Medicine, and who himself has authored numerous publications on proton therapy treatment. See <https://www.med.upenn.edu/apps/faculty/index.php/g20002680/c1744/p16732>.

² It should be noted that the phrase "experimental and investigational" as used by Aetna is a term of art in the insurance industry not a term of art in the medical profession.

approach to Proton Beam Therapy treatment for cancer violates its statutorily-mandated obligation to discharge its fiduciary duty solely in interest of the Plan's participants and beneficiaries exclusively for the purpose of providing benefits and defraying costs.

15. Plaintiffs allege that Aetna's conduct "lulled" them and members of the class into a false sense of security by promising to provide medical treatment for cancer and thereafter failing to do so. As such, Aetna's conduct breached its fiduciary duty. Plaintiffs and the Class are therefore entitled to remedy Aetna's breaches of fiduciary duties pursuant to ERISA's civil enforcement mechanism found in the statute at 29 U.S.C. § 1132(a), to recover benefits due to them under the Plan, enforce their rights under the Plan and to seek a clarification of rights to future benefits, on behalf of themselves and all others who have been prescribed Proton Beam Therapy by doctors, but denied under the Plan for the same, specious reasoning.

II. JURISDICTION AND VENUE

16. This Court has subject matter jurisdiction over this action pursuant to 28 U.S.C. § 1331 (federal question jurisdiction), as it involves claims for breach of fiduciary duty under employee benefit health plans regulated and governed by ERISA.

17. Defendants regularly and systematically conduct business within the Commonwealth of Pennsylvania, and maintain offices in Blue Bell and Philadelphia. Personal jurisdiction is, therefore, properly exercised over the Defendants.

18. Venue is proper in this District pursuant to 28 U.S.C. § 1391 as a substantial part, if not all, of the events and/or omissions giving rise to the Plaintiffs' claims emanated from activities within this jurisdiction, wherein Defendants also conduct substantial business. Furthermore, the Plan and the "policy of insurance" issued by Aetna were all delivered to Plaintiffs in this judicial district.

III. THE PARTIES

19. Plaintiffs Paul Molloy and Jacqueline Molloy are husband and wife and adult citizens of the Commonwealth of Pennsylvania, residing in Newtown Square, Pennsylvania 19073.

20. At all times relevant, Plaintiff Jacqueline Molloy is and has been employed by The Vanguard Group, Inc. (“Vanguard”), working at its location in Malvern, Pennsylvania.

21. As an employee of Vanguard, Plaintiff Jacqueline Molloy is entitled to participate in its employee welfare benefit plan known as “Choice POS II with Aetna Health Fund Benefit Plan” (hereinafter, the “Plan”). As noted above, the Plan is an “employee welfare benefit plan” established by Ms. Molloy’s employer, Vanguard and regulated by ERISA. *See* Aetna 2018 Choice POS II Benefit Plan, prepared exclusively for the Vanguard Group, a true and correct copy of which is attached hereto as Exhibit “A.” *See also* 29 U.S.C. § 1002(1).

22. The Plan is offered and funded by Vanguard and administered by Aetna Life Insurance Company. *See* Exhibit A, at p. 92, “Additional Information.” As such, Aetna is both a “person” and the “administrator” of the Plan as those terms are defined in 29 U.S.C. §§ 1002(9) (person) and 1002(16)(A) (administrator).

23. At all times relevant to this action, Plaintiff Jacqueline Molloy was and is a “participant” of the Plan as that term is defined by ERISA, 29 U.S.C. § 1002(7).

24. At all times relevant hereto, Plaintiff Paul Molloy was and is a “beneficiary” of the Plan as that term is defined by ERISA, 29 U.S.C §1002(8).

25. Defendant Aetna Life Insurance Company (“ALIC”) is a corporation organized and existing under the laws of the State of Connecticut, with its principal place of business located at 151 Farmington Ave., Hartford, Connecticut, 06156. Aetna Life Insurance Company is a wholly-owned subsidiary of Aetna Inc.

26. ALIC is licensed by the Commonwealth of Pennsylvania Department of Insurance to conduct business as an insurance company in the Commonwealth of Pennsylvania.

27. Defendant Aetna Inc. is the parent company of ALIC. It is a corporation organized and existing under the laws of the Commonwealth of Pennsylvania, with its principal place of business at 151 Farmington Ave., Hartford, CT 06156.

28. Upon information and belief, Defendant ALIC, through its parent corporation Aetna Inc., is in the business of providing, administering and insuring health plans to consumers in this judicial district.

29. In addition, Aetna Inc. authored and/or copyrighted the Aetna 2017 Clinical Policy Bulletin (“CPB”) 0270, upon which ALIC and Aetna’s outside reviewers based their denials, as set forth below in paragraphs 44-49 and 78-82, *infra*. See also, Exhibit D.

30. As used in this Complaint, “Aetna” includes both ALIC and Aetna Inc.

31. Aetna is an ERISA “fiduciary” with respect to Mr. and Mrs. Molloy’s plan and the plans of all putative class members in that Aetna is a “person” as defined by the statute and exercises discretionary authority or discretionary control with respect to the management of the plans; exercises discretionary authority or discretionary control with respect to the management or disposition of the assets of the plans; or has discretionary authority or discretionary responsibility in the administration of the plans. See 29 U.S.C. § 1002(21)(A). In addition, Aetna is the Plan’s designated “administrator.”

IV. FACTUAL BACKGROUND

Diagnosis and Recommendation for Proton Beam Therapy

32. Paul Molloy is a 36-year-old man who first began experiencing lightheadedness, tinnitus and bilateral arm-tingling in early 2016. Following a Head CT scan in May 2017 and a

brain MRI, he was diagnosed with a brain tumor (WHO II, low-grade oligodendroglioma) in his right temporal lobe.

33. On June 19, 2017, Mr. Molloy underwent a craniotomy (i.e., brain surgery) of his right temporal lobe at the Hospital of the University of Pennsylvania Department of Radiation and Oncology, which was successful in removing approximately 80% of Mr. Molloy's tumor.

34. Following surgery, his surgical team recommended that he receive post-operative radiation with Proton Beam Therapy.

35. Proton Beam Therapy, as opposed to traditional radiation techniques such as *photon* beam therapy, allows for precision of the proton beam and control of the dosage delivered to the tumor site, while at the same time sparing surrounding healthy cells, tissue or organs from radiation damage.

36. Alternately, *photon* therapy enters the area (in Plaintiff's case, his brain) on the one side and exists the area on the other side, exposing healthy cells, tissue and organs to damage caused by radiation.

37. Research shows that radiation exposure to the hippocampus (which can result from exposing the brain to photon beam treatment) can result in cognitive impairments.

38. Specifically for Mr. Molloy, the use of Proton Beam Therapy would be more likely to spare Mr. Molloy's entire left temporal lobe, including the hippocampus, from exposure to damaging radiation, unnecessary to the treatment of his tumor. As Mr. Molloy is right-handed, the left frontal lobe is his dominant lobe, which controls thought, speech, purposeful movement and personality. *See* Lustig 9/8/2017 Precertification Request, "Assessment" section, a true and correct copy of which is attached hereto as Exhibit "B."

39. Mr. Molloy's physician, Dr. Lustig (the director of the Network Development Program and professor of Clinical Radiation Oncology of the Perelman School of Medicine at the University of Pennsylvania and board-certified therapeutic radiologist at the Hospital of the University of Pennsylvania) specifically advised the use of Proton Beam Therapy, as it:

- "[Is] More accurate than other kinds of radiation, allowing the physician to deliver full or higher doses while sparing surrounding healthy tissues and organs
- Can reduce long term neurocognitive side effects
- Reduces the risk of a second malignancy by reducing the volume of radiated normal tissue
- Protect[s] import [sic] structures of the brain including the hippocampus, hypothalamus, pituitary, optic structures, temporal lobes and cochlea."

Exhibit B, at p. 1.

40. Mr. Molloy's wife, Jacqueline, maintains a health insurance plan through her employer, Vanguard. This plan is administered by Aetna (ID Number W0000027841). Mr. Molloy is a covered beneficiary under his wife's Aetna plan.

41. On September 8, 2017, Dr. Lustig requested precertification from Aetna for Mr. Molloy's proton therapy treatment. With his precertification request, Dr. Lustig submitted his professional assessment, along with a Proton Beam Radiotherapy Precertification Information Request Form, an Ambulatory Precertification Response, and a copy of Mr. Molloy's relevant medical records. *See* Exhibit B.

The Plan

42. Mr. Molloy is and was at all relevant times covered as a beneficiary by the Plan, the relevant terms of which are as follows:

Pp. 3-4: How Your Medical Plan Works

This Aetna Choice POS II medical plan provides coverage for a wide range of medical expenses for the treatment of illness or injury. It does not provide benefits for all medical care...

The plan will pay for covered expenses up to the maximum benefits shown in this Booklet. Coverage is subject to all the terms, policies and procedures outlined in this Booklet. Not all medical expenses are covered under the plan. Exclusions and limitations apply to certain medical services, supplies and expenses. Refer to the *What the Plan Covers*, *Exclusions*, *Limitations* sections and *Schedule of Benefits* to determine if medical services are covered, excluded or limited.

P. 12: Requirements for Coverage

To be covered by the plan, services and supplies must meet all of the following requirements:

1. The service or supply must be covered by the plan. For a service or supply to be covered, it must:
 - Be included as a covered expense in this Booklet;
 - Not be an excluded expense under this Booklet. Refer to the *Exclusions* sections of this Booklet for a list of services and supplies that are excluded.
- ...
3. The service or supply must be medically necessary. To meet this requirement, the medical services or supply must be provided by a physician, or other health care provider, exercising prudent clinical judgment, to a patient for the purpose of preventing, evaluating, diagnosing or treating an illness, injury, disease or its symptoms. The provision of the service or supply must be:
 1. In accordance with generally accepted standards of medical practice;
 2. Clinically appropriate, in terms of type, frequency, extent, site and duration, and considered effective for the patient's illness, injury or disease; and
 3. Not primarily for the convenience of the patient, physician or other health care provider;
 4. And not more costly than an alternative service or sequence of services at least as likely to produce equivalent therapeutic or diagnostic results as to the diagnosis or treatment of that patient's illness, injury or disease.

P. 47: Medical Plan Exclusions

Not every medical service or supply is covered by the plan, even if prescribed, recommended or approved by your physician or dentist. The plan covers only those services and supplies that are medically necessary and included in the *What the Plan Covers* section. Charges made for the following **are not covered** except to the extent listed under the *What the Plan Covers* section or by amendment attached to this Booklet (emphasis added).

P. 50: Experimental or investigational drugs devices, treatment or procedures, except as described in the *What the Plan Covers* section.

P. 75: Definitions: Experimental or Investigational

A drug, a device, a procedure, or treatment will be determined to be **experimental or investigational** if:

- There are insufficient outcomes data available from controlled clinical trials published in the peer-reviewed literature to substantiate its safety and effectiveness for the illness or injury involved; or
- Approval required by the FDA has not been granted for marketing; or
- A recognized national medical or dental society or regulatory agency has determined, in writing, that it is experimental or investigational, or for research purposes; or
- It is a type of drug, device or treatment that is the subject of a Phase I or Phase II clinical trial or the experimental or research arm of a Phase III clinical trial, using the definition of “phases” indicated in regulations and other official actions and publications of the FDA and Department of Health and Human Services; or
- The written protocol or protocols used by the treating facility, or the protocol or protocols of any other facility studying substantially the same: drug; device; procedure; or treatment, or the written informed consent used by the treating facility or by another facility studying the same drug, device, procedure, or treatment states that it is **experimental or investigational**, or for research purposes.”

See Exhibit A.

Aetna’s Pre-Certification Internal Denial

43. On September 8, 2017, within hours of Dr. Lustig’s request, Aetna denied Mr. Molloy’s request for precertification. See Aetna September 8, 2017 “Level 1 Appeal Decision,” a true and correct copy of which is attached hereto as Exhibit “C.”

44. In denying this request, Aetna stated, “The basis for our determination is that Aetna considers proton beam radiotherapy **experimental and investigational** for oligodendroglioma. This is based on the CPB referenced above.” See Exhibit C. The denial also cites Aetna’s “Experimental and Investigational” definition from its Plan (at p. 75, cited *supra*) in its denial.

45. The original denial states it was authored by an “Aetna medical director, board certified in family medicine with a designation of medical doctor and a complaint and appeal registered nurse.” *See* Exhibit C, at p. 2.

46. The CPB Aetna referenced in its denial relates to Aetna’s May 12, 2017 Clinical Policy Bulletin (“CPB”) Number 0270 on Proton Beam and Neutron Beam Radiotherapy, stating that “[m]edical studies have not proven that this procedure is effective for treatment” of Mr. Molloy’s condition. *See* May 12, 2017 Aetna CPB 0270, a true and correct copy of which is attached hereto as Exhibit “D,”³ and can be found in later iterations online at http://www.aetna.com/cpb/medical/data/200_299/0270.html.

47. The 2017 CPB states, in relevant part:

- I. Aetna considers proton beam radiotherapy (PBRT) medically necessary in *any* of the following radiosensitive tumors:
 - Chordomas or chondrosarcomas arising at the base of the skull or cervical spine without distant metastases; or
 - Malignancies in children (21 years of age and younger);
 - Uveal melanomas confined to the globe (i.e., not distant metastases) (the uvea is comprised of the iris, ciliary body, and choroid [the vascular middle coat of the eye]).⁴
- ...
- III. Aetna considers proton beam radiotherapy experimental and investigational for all other indications, including the following indications in adults (over age 21) (not an all-inclusive list) because its effectiveness for these indications has not been established:

48. The list of indications on the 2017 CPB No. 0270 contained approximately 60 exclusions, with “oligodendroglioma” listed among these exclusions.

49. Although the online version of the CPB No. 0270 is listed as being updated on July 29, 2019 and May 9, 2018 (and prior to that, on May 12, 2017), the majority of its studies and

³ The only online version available from 2017 version appears to be a draft from March 9, 2017. Upon information and belief, this CPB does not differ substantially from the May 2017 version.

⁴ This 2017 CPB has since been revised twice (May 9, 2018 and July 29, 2019) and the 2019 version was updated to include coverage for “[l]ocalized unresectable hepatocellular carcinoma (HCC)” in certain medical situations.

peer-reviewed literature still date prior to 2014. It contains only a handful of references to 2017 or 2018 studies.

50. On September 12, 2017, Dr. Lustig appealed Aetna's decision and faxed another precertification request to Aetna on behalf of Mr. Molloy.

51. Aetna responded to this second request on September 13, 2017, upholding its previous decision and citing the same set of factors in its original September 8th denial. *See* Aetna September 13, 2017 Final Appeal Decision, a true and correct copy of which is attached hereto as Exhibit "E."

52. This Decision was authored by a Janet Conway, RN, an Appeals Nurse consultant in Aetna's National Clinical Appeals Unit, and states that an Aetna medical director, board certified in internal medicine and oncology with a professional designation of MD and a registered nurse *participated* in the appeal. *Id.*

Pre-Certification External Review Denial

53. Following the denial of his appeal, Mr. Molloy submitted an External review to MCMC Federal ERO Review Team.

54. Mr. Molloy's extremely thorough letter noted that Proton Beam Therapy is permitted for children under 21 and adults over 65 for the same reasons his physician stated it should be administered to Mr. Molloy. Molloy October 6, 2017 Letter, a true and correct copy of which is attached hereto as Exhibit "F".

55. Mr. Molloy also noted in his appeals that proton beam therapy for primary central nervous system tumors was not, in fact, "experimental and investigational," as recognized by the American Society for Radiation Oncology ("ASTRO"), in other recent studies, and by Mr. Molloy's own doctors.

56. Indeed, Mr. Molloy noted that other insurers, such as Blue Cross and Medicaid, cover proton beam therapy. *See* Nikhil G. Thaker, MD et al., “Variations in Proton Therapy Coverage in the State of Texas: Defining Medical Necessity for a Safe and Effective Treatment, *International Journal of Particle Therapy* (2016), 500-508 (stating BCBS-TX and Medicare consider Proton Beam Therapy medically necessary for cancers of the central nervous system and for localized prostate cancers)⁵.

57. Mr. Molloy stated that Proton Beam Therapy was not investigational or experimental because: (1) it has been used to treat patients since the mid-1950s; (2) was approved for use in 1988 by the U.S. Food and Drug Administration; (3) Medicare and Medicaid began covering the procedure in 2000. Exhibit E, at 2.

58. Mr. Molloy’s letter also detailed multiple studies from 2012, 2015, 2017 proving specifically that patients with low-grade gliomas like Mr. Molloy’s tolerated Proton Beam Therapy. *Id.*

59. Three of the cited studies demonstrated that Proton Beam Therapy is more likely to produce superior therapeutic results to traditional photon therapy, especially because of its reduced negative effect on the surrounding healthy organs and tissues caused by radiation damage:

- *Proton Therapy for Low Grade Gliomas: Results from a Prospective Trial*⁶: “Proton radiation therapy offers an alternative to photon-based radiation therapies as a means of markedly reducing excess doses to surrounding normal tissue, thereby potentially mitigating adverse effects on neurocognitive and neuroendocrine function for patients with brain tumors.”
- *Mayo Clinic: Clinical Case of Individuated Use of Proton Beam Therapy*⁷: “And because proton beam therapy can spare healthy tissue from radiation exposure, as compared to the

⁵ Available at <https://theijpt.org/doi/pdf/10.14338/IJPT-15-00029.1>, at Table 2.

⁶ Helen A. Shih, MD, et. al., “Proton Therapy for Low Grade Gliomas: Results from a Prospective Trial,” *Cancer*, 13 Jan. 2015, found at <https://onlinelibrary.wiley.com/doi/full/10.1002/cncr.29237>

⁷ Mayo Clinic, found at <https://www.mayoclinic.org/documents/the-clinical-case-for-individualized-use-of-proton-beam-therapy/doc-20145258>.

best x-ray techniques, it is widely believed that this will yield to a lower risk of radiation-induced cancers... Some estimates are that proton beam radiation can decrease the risk of a radiation-induced cancer by as much as 10-fold.”

- *Should Randomized Clinical Trials Be Required for Proton Radiotherapy?*⁸:
 - “In brief, the arguments for use of protons in radiation therapy are as follows: (1) Owing primarily to their depth dose characteristics, the dose distributions that can be achieved with protons are in almost all cases superior to those possible with x-rays; (2) there is virtually no difference in tissue response per unit dose between protons of therapeutic energies as compared with x-rays, so that the only relevant differences are physical; and (3) radiation delivered to normal tissues causes damage to them, just as it does to tumors, and the severity of that damage increases with increasing doses. None of these points are contested by any of the critics of the use of proton beam therapy, as these points are demonstrated facts.”
 - “It is therefore hard to imagine how any objective person could avoid the conclusion that there is, at the very least, a high probability that protons can provide superior therapy to that possible with x-rays in almost all circumstances. It is primarily for this reason that the practitioners of proton beam therapy have found it ethically unacceptable to conduct RCTs [randomized clinical trials] comparing protons with x-rays. Such a comparison would not meet a central requirement for performing RCTs, namely that there be equipoise between the arms of the trial.”
 - “Of course, it is really all about money. Can anyone seriously believe that, if protons were cheaper than x-rays, there would be similar objections raised as to their immediate and widespread use?”

60. The letter also cited to a July 2017 American Society for Radiation Oncology (ASTRO)⁹ article¹⁰ describing ASTRO’s revised Proton Beam Therapy Model Policy that detailed which cancer diagnoses met ASTRO’s evidence-based standards and should be covered by private insurers and Medicare. *Id.* At 3.

⁸ Goitein, Michael, James D. Cox, “Should Randomized Clinical Trials Be Required for Proton Radiotherapy?” *Journal of Clinical Oncology*, 2008, 26(2), pp. 175–176, found at <https://ascopubs.org/doi/10.1200/JCO.2007.14.4329>

⁹ According to its website, ASTRO is the premier radiation oncology society in the world, with more than 10,000 members who are physicians, nurses, biologist, physicists, radiation therapists, dosimetrists and other health care professionals who specialize in treating patients with radiation therapies. Upon information and belief, radiation oncologists rely on ASTRO Guidelines to guide their prescriptions.

¹⁰ Available at <https://www.astro.org/News-and-Publications/News-and-Media-Center/News-Releases/2017/ASTRO-updates-insurance-coverage-recommendations-f>

61. In its Revised Proton Beam Therapy Model Policy, ASTRO stated that “PBT is considered reasonable in instances where sparing the surrounding tissue cannot be adequately achieved with photon-based radiotherapy and is of added clinical benefit to the patient.” *See* ASTRO Model Policies, Proton Beam Therapy, a true and correct copy is attached hereto as Exhibit “G,” at 4.¹¹ ASTRO lists four instances, one of which as when “[t]he target volume is in close proximity to one or more critical structures and a steep dose gradient outside the target must be achieved to avoid exceeding the tolerance dose to the critical structure(s).” *Id.*

62. ASTRO also updated its Group 1 indications, which represent the clinical scenarios **that frequently support the use of proton therapy based on medical necessity and published clinical data.** These indications include:

- Ocular tumors, including intraocular melanomas
- Tumors that approach or are located at the base of skull, including but not limited to:
 - Chordoma
 - Chondrosarcomas
- Primary or metastatic tumors of the spine where the spinal cord tolerance may be exceeded with conventional treatment or where the spinal cord has previously been irradiated
- Hepatocellular cancer
- Primary or benign solid tumors in children treated with curative intent and occasional palliative treatment of childhood tumors when at least one of the four criteria noted above apply
- Patients with genetic syndromes making total volume of radiation minimization crucial such as but not limited to NF-1 patients and retinoblastoma patients
- **Malignant and benign primary CNS tumors**
- Advanced (eg, T4) and/or unresectable head and neck cancers
- Cancers of the paranasal sinuses and other accessory sinuses
- Non-metastatic retroperitoneal sarcomas
- Re-irradiation cases (where cumulative critical structure dose would exceed tolerance dose)

Id., at 5.

¹¹Also available at https://www.astro.org/uploadedFiles/MAIN_SITE/Daily_Practice/Reimbursement/Model_Policies/Content_Pieces/ASTROPBTModelPolicy.pdf

63. Plaintiff himself suffered from a malignant CNS tumor.

64. This change to the ASTRO guidelines was made three months (June 2017) *before* Aetna's initial September 8, 2017 denial of Mr. Molloy's precertification request.

65. Still, MCMC denied Mr. Molloy's External Review on **October 6, 2017**. *See* October 6, 2017 Denial, a true and correct copy of which is attached hereto as Exhibit "H."

66. In its denial, MCMC stated: "there is insufficient clinical data in the medical literature to show that proton is equivalent or superior to other treatment options such as photon therapy for primary brain tumors." *Id.*, at 2.

67. It also held Proton Beam Therapy to be **investigational/experimental** because, according to the Aetna Summary Plan Description, "it is a type of drug, device or treatment that is the subject of a Phase I or phase II clinical trial or the experimental or research arm of a Phase III clinical trial."

68. Finally, MCMC stated that Proton Beam Therapy **was not medically necessary** because it is "more costly than an alternative service or sequence of services at least as likely to produce equivalent therapeutic or diagnostic results as to the diagnosis or treatment of that patient's illness, injury, or disease." *Id.*

69. The MCMC Reviewer most recent reference was the same 2015 trial cited by Mr. Molloy in his appeal submissions, but did not cite the more recent 2017 ASTRO Model Policy guidelines, or *any* academic study or reference post-dating that 2015 study.

70. The MCMC Reviewer notes that he is board certified in Radiation Oncology, and that he is a member of ASTRO, as well as the Radiological Society of North America. Still, this Reviewer issued his/her decision without any consideration of the new 2017 ASTRO Model Policy, adopted at least four months prior to MCMC's rejection of the appeal.

Post-Service Claim Submissions and Denials

71. As proton therapy was Mr. Molloy's only valid option to ensure that his surrounding brain tissue be spared radiation, Mr. Molloy and his family paid for his treatment out-of-pocket, at a discounted cost of approximately \$50,000.

72. Mr. Molloy received proton beam therapy radiation treatment for his brain tumor at HUP starting in October 2017 and finishing in December 2017.

73. Mr. Molloy submitted a post-service claims and appeals for reimbursement to Aetna on January 4, 2018 and July 20, 2018; submitting his similar extensive documentation and research on proton beam therapy.

74. Aetna denied both the Level 1 and Final Appeals on January 25, 2018 and August 7, 2018, finding the services to be "experimental or investigational." *See* Jan. 25, 2018 and August 7, 2018 Aetna Denial Letters, attached hereto as Exhibit "I" and "J."¹²

75. Then, Mr. Molloy submitted his external review to Independent Medical Expert Consulting Services ("IMEDECS").

76. On October 10, 2018, IMEDECS denied this external review appeal, also concluding that the treatment requested is "experimental/investigational." *See* October 10, 2018 IMEDECS Letter, attached hereto as Exhibit K.

77. Interestingly, the IMEDECS reviewer also stated that "The American Society for Radiation Oncology (ASTRO) emerging technology committee report on proton therapy specifically states that more clinical data are needed to fully establish the role of proton beam

¹² The first denial was authored by "an Aetna medical director, board certified in oncology medicine and a complaint and appeal nurse," and the second denial was authored by "an Aetna medical director, board certified in Internal Medicine with a professional designation of Doctor of Medicine (MD), a complaint and appeal nurse, with a professional designation of Registered Nurse "RN), and a complaint and appeals analyst." *See* Exhibits I and J. *No one* certified in Radiation Oncology participated in these internal appeals.

therapy in CNS tumors.” However, the reviewer does not cite any date for this committee report, but internet searches reveal this report to have been published in 2012. See Allen AM, “An evidence based review of proton beam therapy: the report of ASTRO’s emerging technology committee,” *Radiother Oncol.* 2012 Apr;103(1):8-11.¹³ It is likely that the IMEDECS Reviewer lifted this directly from Aetna’s CPB No. 0270, which itself does not contain the updated 2017 ASTRO Model Policy Guidelines.¹⁴

78. In fact, as stated *supra*, though the CPB No. 0270 cites to approximately 100 studies from 2006-2014, it only contains a handful of studies and peer-reviewed literature references after that year, despite the CPB being reviewed and revised every year since 2008.

79. And yet, though the IMEDECS reviewer’s denial report was prepared more than a year after ASTRO adopted the new Model Policy (which actually recommends the use of proton therapy to treat CNS tumors), the reviewer makes no mention of the new 2017 ASTRO Model Policy, or any post-2015 studies at all. *Id.*, at 3.

80. Mr. Molloy submitted his final, external review to the Medical Review Institute of America, LLC (“MRIoA”) on January 3, 2019. MRIoA upheld the previous denials and issued its final denial on February 7, 2019 based on the **experimental/investigational exclusion** and Aetna CPB Number 0270. See Feb. 7, 2019 Denial, a true and correct copy of which is attached hereto as Exhibit “L.”

81. In sum, Aetna is responsible for and committed the course of conduct described herein, including but not limited to the following:

¹³ Available at <https://www.ncbi.nlm.nih.gov/pubmed/22405807>.

¹⁴ The most recent updated version of Aetna’s CPB No. 00270 from July 29, 2019 does reference the 2017 ASTRO updated guidelines, but states that the “ASTRO model policy states that it is not a clinical guideline and that it was created for insurance reimbursement purposes.”

- a. Aetna has failed to properly update Clinical Policy Bulletin No. 0270 (“CPB No. 0270”), Proton Beam and Neutron Beam Radiotherapy, as it relies upon outdated medical evidence and ignores contemporary medical evidence, insofar as CPB No. 0270 provides that Proton Beam Therapy is covered for insured members in only three, extremely limited, circumstances:
 - Chordomas or chondrosarcomas arising at the base of the skull or cervical spine without distant metastases; or
 - Malignancies in children (21 years of age and younger);
 - Uveal melanomas confined to the globe (i.e., not distant metastases) (the uvea is comprised of the iris, ciliary body, and choroid [the vascular middle coat of the eye]).
- b. Aetna implemented policies and procedures for prior authorization review and the adjudication of insured members’ claims that provide for an inadequate review of clinical records by its medical directors prior to rendering a determination of coverage.
- c. Aetna compounds its bad faith breach of fiduciary duties, and confounds learned health care providers, by having CPB No. 0270 reviewed and applied to insured members’ requests for prior authorization and in the adjudication of insured members’ claims by medical directors who are unqualified to render determinations of coverage for Proton Beam Therapy¹⁵, including medical directors who are not board certified in the requisite specialty, and yet are charged with making life and death decisions for members who are entirely reliant upon the Plan for timely access to medically necessary services.
- d. By placing CPB No. 0270 in the hands of medical directors who are not qualified to render opinions as to the medical necessity of Proton Beam Therapy; who lack

¹⁵ None of the internal Aetna denials were authored by physicians board certified in radiation oncology.

the education, training and experience to appreciate factors in a given case that indicate the medical necessity for Proton Beam Therapy; who are unaware of contemporary medical evidence in the requisite specialty indicating the medical necessity for Proton Beam Therapy; and who follow the inadequate policies and procedures for clinical review, Aetna categorically denies all prior authorization requests and claims for Proton Beam Therapy for all types of cancers on CPB No. 0270's "not indicated" list, including brain tumors.

82. In other words, the external reviews simply rubber-stamped Aetna's prior denials using Aetna's own incomplete, arbitrary, medically unreasonable and internally inconsistent Policy, without conducting any *truly* independent evaluations of whether Proton Beam Therapy is a proven and effective treatment for Plaintiff's diagnosed cancer.

83. Aetna has chosen to rely on the opinions of its medical reviewers, despite their lack of requisite qualifications and expertise in the specific radiation oncology field, and/or obvious ignorance of current relevant medical opinion¹⁶, rather than relying on the opinions of *their patient's* own esteemed and properly board-certified health care providers.

¹⁶ Although too recent to have been included in Mr. Molloy's appeal submissions, a study published in the most recent edition of Practical Radiation Oncology (2019) examined 141 patients with either World Health Organization 2007 grade I to II low-grade gliomas, or WHO 2007 grade III gliomas (with isocitrate dehydrogenase 1 mutation) who were treated with Proton Beam Therapy. See Sophia C. Kamran MD, *et al.*, "Patterns of Failure Among Patients with Low-grade Glioma Treated with Proton Radiation Therapy," Practical Radiation Oncology (2019) 9, e356-e361, a true and correct copy of which is attached hereto as Exhibit "M." While recognizing that it was a single-institution, retrospective study, the researchers noted: "To our knowledge, this was the largest study of LGGs treated with [Proton Beam Therapy]." See *id.* at e359. The researchers highlighted that "[p]atients with LGG have a relatively long survival and are predominantly young adults; therefore treatment that minimizes toxicities in this patient population has significant impact on these individuals and their families, whom they are often supporting." *Id.* "Our results demonstrate that proton beam therapy is effective as a treatment modality for LGGs, with excellent local control rates... This study is encouraging because despite the drop-off dose gradient associated with protons, current treatment margins are adequate and do not translate into more treatment failures. Therefore, PRT is a reasonable treatment option in this relatively young patient population to reduce excess radiation dose to the collateral brain and other normal tissues while providing disease control comparable to photon experiences." *Id.*

84. Mr. Molloy was forced to incur approximately \$50,000 for Proton Beam Therapy treatment, without any assistance from Aetna. Fortunately, Mr. Molloy, unlike many of the class members, was able to afford such a procedure. Mr. Molloy has had no evidence of recurrence of the cancer for over a year-and-a-half, and without any of the harmful side effects that photon therapy can cause.

85. Mr. Molloy now pursues this fight for change, individually and on behalf of the Class Members, particularly those less fortunate and unable to bear the economic expense of Proton Beam Therapy treatment, so that Aetna's insured members suffering with cancer can focus on their recovery rather than on the extreme and outrageous anxiety and distress of wrongful coverage denials and the crippling cost of care.¹⁷

86. Under ERISA, Plaintiffs and the Class members are entitled to equitable and declaratory relief enjoining the application of the Aetna CPB Number 0270 and denying benefits coverage for Proton Beam Therapy prescribed by a doctor and awarding other such relief the Court finds appropriate.

CLASS ACTION ALLEGATIONS

87. Plaintiff brings this action individually and all others similarly situated as a Class Action pursuant to Federal Rules of Civil Procedure Rule 23. Plaintiff incorporates herein, by reference, all other paragraphs and footnotes of this Class Action Complaint as if fully set forth herein at length.

¹⁷ As United States District Court Judge Robert N. Scola, Jr. (S.D. Fla.) recently wrote in his recent April 29, 2019 Order recusing himself from *Cole v. United Healthcare Insurance Co.*, 1:19-cv-21258 (Doc. 6) (a class action suit against insurer of wrongly denying coverage for Proton Beam Therapy for prostate cancer treatment) due to his own prostate cancer diagnosis: "It is undisputed among legitimate medical experts that proton radiation therapy is not experimental and causes much less collateral damage than traditional radiation. To deny a patient this treatment, if it is available, is immoral and barbaric." *Id.* See J. Scola Order, a true and correct copy of which is attached hereto as Exhibit "N."

88. Pursuant to Rule 23(b)(1) and (b)(2), Plaintiff seeks certification of a class defined as follows:

All persons covered under ERISA-governed plans administered or insured by Aetna whose requests for medically prescribed Proton Beam Therapy were denied at any time within the applicable statute of limitations, or whose requests for Proton Beam Therapy will be denied in the future, based upon a determination by Aetna that Proton Beam Therapy is not medically necessary, or is experimental or investigational.

89. The Class claims all derive directly from a single course of conduct by Defendants. Defendants engaged in uniform and standardized conduct toward the Class. They did not differentiate, in degree of care or candor, their actions or inactions among individual Class members. The objective facts are the same for all Class members. Within each Claim for Relief set forth below, the same legal standards under federal law govern. Accordingly, Plaintiff brings this lawsuit as a Class Action on his own behalf and on behalf of all other persons similarly situated as members of the proposed Classes pursuant to Federal Rule of Civil Procedure 23.

90. This action has been brought and may be properly maintained as a Class Action under the provisions of Federal Rules of Civil Procedure Rule 23 because there is a well-defined community of interest in the litigation and the proposed class is easily ascertainable. This action satisfies the numerosity, commonality, typicality, adequacy, predominance, and superiority requirements of those provisions.

- A. **Numerosity**: Upon information and belief, potential members of the proposed class as defined are so numerous that joinder of all the members of the proposed class is impracticable. While the precise number of proposed class members has not been determined at this time, Plaintiff is informed and believes that there are a substantial number of individuals covered under plans insured or administered by Aetna who have been similarly affected.
- B. **Commonality**: Common questions of law and fact exist as to all Class members and predominate over any questions solely affecting individual

Class members. Among the questions of law and fact common to Plaintiff and the Class Members are:

- a. Whether Aetna's use of its medical policy related to Proton Beam Therapy violates its statutorily-mandated requirement to act as a fiduciary with respect to the Plan solely in the interest of the participants and beneficiaries and for the exclusive purpose of: (1) providing benefits to participants and their beneficiaries; and (2) defraying reasonable expenses of administering the plan.
 - b. What criteria Defendants actually consider in their decision that Proton Beam Therapy is not medically necessary, or experimental and/or investigational for certain types of cancer, and whether that decision-making process was a separate breach of their fiduciary duty;
 - c. Why Defendants rely on medical directors who are unqualified to render determinations of coverage for Proton Beam Therapy, including medical directors who are not board-certified in the requisite specialty, and whether that reliance was a separate breach of their fiduciary duty; and
 - d. Whether Aetna's continued denial of Proton Beam Therapy to patients whose own physicians have determined the procedure to be medically necessary for their types of cancer is a separate breach of its fiduciary duty.
- C. **Typicality:** Plaintiffs' claims are typical of the claims of Class Members because every cancer patient who was prescribed Proton Beam Therapy by their physicians was denied by Aetna for the reason that Proton Beam Therapy was not medically necessary or is experimental or investigational.
- D. **Adequacy of Representation:** Plaintiffs will fairly and adequately protect the interests of the proposed Class. Plaintiffs have retained counsel competent and experienced in complex class action litigation and with adequate resources to assure the interests of the Class will not be harmed. The named Plaintiffs are typically situated and have no conflict of interest with the Class as a whole.
- E. **Class Action Maintainable Under Rule 23(b)(2):** By misrepresenting the scope of the insurance coverage provided by Aetna, its conflicts of interest and breaches of fiduciary duty, Aetna has acted or refused to act on grounds generally applicable to the Class, thereby making the claims for reimbursement, injunctive, and declaratory relief sought herein the appropriate remedies for the Class.

- F. **Class Action Maintainable under Rule 23(b)(3):** A class action is appropriate here because common questions of law and fact predominate over any individual questions affecting only individual members. Class treatment is superior to the alternatives for the fair and efficient adjudication of the controversy alleged herein. Such treatment will permit a large number of similarly situated individuals to prosecute their common claims in a single form simultaneously, efficiently, and without the duplication of effort and expense that numerous individual actions would entail. No difficulties are likely to be encountered in the management of this class action that would preclude its maintenance as a class action, and no superior alternative exists for the fair and efficient adjudication of this controversy. Without a class action, Defendants will remain free from responsibility for its bad faith breach of fiduciary duties. Without class treatment, Plaintiff and similar entities will be forced to conduct protracted, piecemeal litigation that might risk establishing conflicting standards of conduct and/or determinations.
- G. **Ascertainability:** The Class Members are ascertainable as all Defendants can identify every single class member from their own records. Accordingly, mere ministerial acts on the part of Defendants and the potential Class Members will be necessary to ascertain all potential Class Members.

91. In this action, Plaintiffs seek all statutorily appropriate and available relief from Aetna for violating its duty to act as an ERISA fiduciary with respect to its plan participants, for the reasons set forth below:

COUNT I: BREACH OF FIDUCIARY DUTY

92. Plaintiff and the Class Members incorporate by reference the foregoing paragraphs as though fully set forth herein.

93. As set forth herein, Plaintiff and the Class Members are participants in or beneficiaries of employee welfare benefit plans or employee benefit plans administered and/or underwritten by Aetna and governed by ERISA.

94. Aetna acts as an ERISA fiduciary with respect to the administration and claims decisions of the group health benefit plan it issues to employers, such as the Plan and the Class plans, within the meaning of 29 U.S.C. § 1109(a) and 1002(21)(A). With respect to these plans,

Aetna exercises discretionary authority or control respecting management of the plans, and exercises authority or control respecting management or disposition of the plans' assets.

95. Aetna has the authority, and actually exercises the authority, to fund plans or administer self-funded plans (like the Plan), make decisions on claims for benefits and appeals thereof, and to write checks for benefits.

96. As an ERISA fiduciary, Aetna must act with the utmost prudence and loyalty in communicating to plan participants and beneficiaries and in administering their claims under the plan, and must otherwise comply with the requirements of ERISA, and with terms and conditions of its ERISA plans themselves, in making benefit determinations and processing claims on behalf of plan participants and beneficiaries. Specifically, Aetna is statutorily mandated to act as a fiduciary with respect to the Plan solely in the interest of the participants and beneficiaries and for the exclusive purpose of: (1) providing benefits to participants and their beneficiaries; and (2) defraying reasonable expenses of administering the plan.

97. Due to this breach of fiduciary duty, Aetna violated its own statements to plan participants and beneficiaries to the contrary when it stated that it would, in fact, deliver access to medically necessary healthcare for the treatment of cancer. *See* 29 U.S.C. § 1104(a)(1)(A).

98. In addition, Aetna must discharge its fiduciary duty “with the care, skill, prudence, and diligence under the circumstances then prevailing that a prudent man acting in a like capacity and familiar with such matters would use in the conduct of an enterprise of a like character and with like aims.” *See* 29 U.S.C. § 1104(a)(1)(B).

99. Aetna repeatedly violated these obligations and duties to Plaintiffs and the Class Members during the class period in part by the following conduct:

1. Implementing Clinical Policy Bulletin No. 0270: Proton Beam and Neutron Beam Radiotherapy, which relies upon outdated medical evidence, ignores

contemporary medical evidence, and relies more heavily on actuarial calculation of risk pools;

2. Having Clinical Policy Bulletin No. 0270 reviewed and applied to insured members' requests for prior authorization, and in the adjudication of insured members' claims by medical directors who are unqualified to render determinations of coverage for Proton Beam Therapy, including medical directors who are not board certified in the requisite specialty; and
3. By continuing to put its financial interests above those of the Plan participants and beneficiaries to the detriment of those participants and beneficiaries as opposed to fulfilling its duty to act solely for the benefit of the Plan's participants and beneficiaries by providing them benefits.

Because Aetna has categorically and improperly denied Paul and other Class Members' requests for Proton Beam Therapy, Aetna has breached, and continues to breach, its fiduciary duty to Plaintiffs and the Class.

100. Pursuant to 29 U.S.C. § 1132(a), Plaintiff and the Class are entitled to enforce ERISA and hold Aetna liable for its breaches of fiduciary duty. As such, Plaintiffs and the Class seek equitable and remedial relief as follows:

1. An injunction compelling Aetna to:
 - Retract its categorical denials for Proton Beam Therapy;
 - Provide notice of said determination in the form and manner required by ERISA to all Class Members who have had prior authorization requests or claims for Proton Beam Therapy denied;
 - Re-evaluate all prior authorization requests or claims for Proton Beam Therapy by Plaintiff and the Class Members under an ERISA-compliant procedure and, where warranted, reimburse Plaintiff and the Class Members for amounts incurred for Proton Beam Therapy as a result of coverage denials in violation of ERISA;
 - An accounting of any profits made by Aetna from the monies representing the improperly denied claims and disgorgement of any profits Aetna may have realized by virtue of its violations of ERISA and other fiduciary breaches;

- Such other equitable and remedial relief as the Court may deem appropriate; and
- Attorneys' fees and costs of litigation.

REQUEST FOR RELIEF

WHEREFORE, Plaintiffs individually and on behalf of the Class Members requests relief as follows:

101. An Order certifying the proposed Class, appointing the Molloyes to represent the proposed Class, and designating the Molloyes' counsel as Class Counsel;

102. An Order declaring that Aetna's practices described herein violate ERISA and its ERISA-based fiduciary duties;

103. Injunctive and reimbursement relief as described and requested above;

104. An Order awarding attorneys' fees and costs of litigation for this action in amounts to be determined by the Court;

105. Payment of pre-judgment and post-judgment interest as allowed under ERISA; and

106. For such other and further relief as this Court may deem just and proper.

DATED: AUGUST 28, 2019

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